FILED
NOV 24 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF ON BEHALF OF PFIZER HOSPITAL PRODUCTS GROUP, INC. AND PFIZER INC. AS AMICI CURIAE

RUDOLF E. HUTZ
Counsel of Record
R. ERIC HUTZ
CONNOLLY, BOVE, LODGE & HUTZ
1220 Market Street
Wilmington, Delaware 19801
(302) 658-9141
Counsel for Amici Curiae Pfizer Hospital Products Group, Inc. and Pfizer Inc.

Of Counsel:
PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd Street
New York, NY 10017

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTION PRESENTED

Did Congress, in enacting 35 U.S.C. § 271(e)(1), which specifically exempts from infringement certain activities involving "drugs or veterinary biological products," also exempt activities involving all other FDA-regulated, nondrug products, including medical devices?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

No. 89-243

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

---

BRIEF ON BEHALF OF PFIZER HOSPITAL PRODUCTS GROUP, INC. AND PFIZER INC. AS AMICI CURIAE

INTEREST OF AMICI

Pfizer Hospital Products Group, Inc. and Pfizer Inc. (collectively "Pfizer") are research-based manufacturers of medical devices and drugs. For many years, Pfizer has conducted research and development into such products for which it has received hundreds of United States Patents.

Pfizer's brief is being filed in support of the position of the Petitioner and urges this Court to reverse the decision below. Counsel for the Petitioner and for the Respondent have both consented in writing to the filing of this brief.

As a substantial patent owner, Pfizer has enjoyed the incentives offered by the United States Patent System in return for its research expenditures and innovation in the cure and alleviation of conditions destructive of the health and well-being of man. An important part of Pfizer's rights includes patents directed to medical devices which make up a significant portion of its sales in the United States.

In the decision below, the Court of Appeals for the Federal Circuit held that the infringement exemption set forth in 35 U.S.C. § 271(e)(1) applies to medical devices as well as to drugs and veterinary biological products. Unlicensed use and sale of medical devices were thereby authorized. Patents directed to a wide variety of lifesaving and quality-of-life-enhancing devices can now be practiced without the owner's consent, thereby reducing the reward, and hence the incentive, to undertake the enormous expense to develop and market new products.

Pfizer possesses a unique historical perspective as an innovator and marketer of both medical devices and drugs which enables it to speak knowledgeably regarding the differences in the approval processes and the heavy impact of the decision below on medical device innovation. Pfizer believes that this perspective and its experience in day-to-day dealings with the applicable Federal Laws governing sale of these products will assist the Court in better understanding the competing policies and statutory compromises intended by Congress when it enacted the Drug Price Competition and Patent Term Restoration Act of 1984 ("1984 Act"). The information possessed by Pfizer is directly relevant to the reasons why Congress limited Section 271(e)(1) to drugs and did not extend its reach to include medical devices. The court below did not appreciate these distinctions when it concluded that there was no logical reason for treating drugs separately from medical devices, and it did not understand the substantial effect its decision would have on the medical device industry.

ARGUMENT

The decision below should be reversed because it is based on a misreading of clear congressional intent as well as the decision, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984) ("Roche"), which Congress overruled when it enacted 35 U.S.C. § 271(e)(1). The 1984 Act simply does not say what the Federal Circuit claims it does, and the intent of the Congress behind the act belies the court's legally erroneous interpretation. The Federal Circuit decided an issue of pure statutory interpretation. Its decision evidences a lack of understanding of the FDA approval process for drugs as contrasted to medical devices and the competing policies and statutory compromises intended by Congress when it passed the 1984 Act.

I. CONGRESS DID NOT INTEND TO OVERRULE *ROCHE v. BOLAR* GENERALLY, BUT ONLY TO THE EXTENT NECESSARY TO PROMOTE OTHER POLICIES

The Federal Circuit properly stated that Section 271(e)(1) was enacted to overrule *Roche* (Pet. App. 5a).[1] The court, however, failed to recognize that the *Roche holding* (as contrasted with *dicta* and *underlying rationale*) was a narrow one relating to "the limited use of a patented drug for testing and investigation strictly related to FDA drug approval" (*Roche*, 733 F.2d at 861) Congress understood that *Roche's* holding was so limited when it considered and enacted Section 271(e)(1). See Part 1 at 45-46 and Part 2, at 8 and 27 of H.R.Rep.

---

[1] "Pet. App." refers to the Appendix filed by Petitioner, Eli Lilly and Company.

No. 857, 98th Cong., 2d Sess. Parts 1 and 2 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News 2647.[2]

In reaching its erroneous conclusion to expand the reach of § 271(e)(1) beyond its literal meaning and the narrow intent of Congress, the Federal Circuit cited no legislative history whatsoever and it failed to recognize that the 1984 Act was based upon a desire to promote two significant congressional policies, neither of which *per se* involved overruling *Roche*.

First, the 1984 Act contained provisions for patent term restoration for drugs, medical devices, food additives and color additives. Second, the 1984 Act authorized abbreviated testing procedures for regulatory approval of generic substitutes for patented drugs so that generic drug substitutes could be marketed promptly after expiration of patents covering the drug. These statutory provisions for expedited marketing of generic substitutes applied to drug products *only*. There were no comparable provisions for abbreviated testing for "generic" medical devices.[3] Under the *Roche* holding, abbreviated testing procedures would constitute patent infringement, and so Congress had to make a very limited exception to the law of infringement to carry forward its second policy objective.

Without question, Congress intended 35 U.S.C. § 271(e)(1) to apply to drugs only because Congress, in enacting the 1984 Act, reasoned as follows: (1) patent term restoration for drugs, medical devices, food additives and color additives was, in and of itself, a desirable

[2] The narrow Congressional focus in § 271(e)(1) is confirmed by subsequent amendments and proposed amendments to this section which are product specific and would be unnecessary were the Federal Circuit's view correct (See, for example, Pub. L. No. 100-670, 102 Stat. 3971 (Nov. 16, 1988)).

[3] The legislative history of the 1984 Act shows no significant input by the manufacturers of "generic" medical devices.

objective; (2) abbreviated testing procedures limited to generic substitutes of patented drugs to permit prompt marketing after patent expiration was also a desirable objective; and (3) in order to realize its second objective, 35 U.S.C. § 271 had to be amended (as in 35 U.S.C. § 271(e)(1)) for patented *drugs* inventions only.

II. THE APPROVAL PROCESSES FOR DRUGS AND MEDICAL DEVICES ARE DISTINCTLY DIFFERENT; UNLIKE DRUGS, THE IMPACT OF § 271(e)(1) IS SIGNIFICANT WHEN APPLIED TO MEDICAL DEVICES

Before new drugs can be marketed, they must receive premarket approval by the FDA, including a showing of safety and effectiveness (21 U.S.C. § 355). Prior to the 1984 Act, even generic copies of prior approved drugs generally necessitated submission of the manufacturer's own clinical data to obtain regulatory approval. In 1984, Congress established an abbreviated procedure for obtaining approval of such generic drugs (21 U.S.C. § 355(j)) —the manufacturer must show only "bioequivalency" to an approved drug, i.e., that it has the same "rate and extent of absorption" into the blood stream. 21 U.S.C. § 355(j)(7)(B)(i).[4]

A test for "bioequivalency" typically involves tests on a limted number of volunteers, who do not have the disease for which the drug is intended. These drugs are often administered on a one time basis and do not remain in the volunteers' system after the effects have dissipated. The volunteers are not candidate customers for the patent owner's product, and they are not charged for the drug. The patent owner loses no sales through third party testing of this sort. Thus, the impact of such tests on the patent owner's commercial interests is minimal,

[4] A generic manufacturer could conduct full clinical trials and submit its own data in seeking approval but given the faster and far less expensive "abbreviated" option, it is unlikely that any would do so.

and Congress determined the impact to be "*de minimis*" (H.R. Rep. No. 857, Part 2, at 30).

By contrast, there is no "abbreviated" procedure for medical devices. Compliance with premarket approval requirements for medical devices includes full-scale clinical trials. Patients with the underlying disease or condition are actually treated and, for many devices, this includes permanently implanting the device so that the treated patient is thereafter unavailable as a customer for the patent owner. Where a diagnostic machine is involved, particularly where the cost is high and the number of potential customers is small, each third-party investigational machine becomes a lost sale for the patent owner.

Manufacturers of investigational devices being tested for approval may charge for their use even though such sales are of products squarely within the scope of a valid patent owned by another (21 C.F.R. § 812.7(b)). The studies frequently involve the participation of leading physicians and medical institutions and such skilled participants are thus lost to the patent owner for his use in similar studies. The manufacturer of the investigational device may use these studies to enhance its reputation for innovation and inventiveness even though the device in question was invented by another and is literally covered by its valid patent.

In short, clinical trials by those who would be infringers but for the decision at issue can deny a medical device patent holder millions of dollars in lost sales and enhance the reputation of a competitor, yet the patent owner has no recourse. No such substantial economic impact occurs during bioequivalency drug testing, a fact recognized by Congress in its discussion of the 1984 Act. See H.R. Rep. No. 857, Part 2, at 8 and 27-30; *Id.* Part 1, at 46. The facts of this case are a perfect illustration of the significant harm caused the patent owner by immunizing "testing" activity from the reach of the law even though such testing is squarely within the claims of a patent the district court held was valid and otherwise enforceable. See Pet. App. 12a-13a.

III. THE DECISION BELOW ADVERSELY IMPACTS ON A SIGNIFICANT UNITED STATES INDUSTRY OF IMMENSE IMPORTANCE TO THE PUBLIC

Medical devices, as defined by 21 U.S.C. § 321(h) and 360(e) encompass a wide variety of products ranging from simple to very sophisticated machinery such as cardioverter defibrillators, orthopedic products, CAT-scans, x-ray and ultrasound machines, and other life-saving devices.

Research and development of such devices are extraordinarily expensive as are the studies necessary to approve such products for sale. Businessmen will not invest to bring these products to the market unless there is a reasonable assurance that a copiest cannot be rewarded at the expense of the innovator.

The effect of the Federal Circuit's opinion is to significantly devalue patent protection in the medical device field and, consequently, to provide a disincentive for innovation, technological development and investment which benefit the health and well-being of the public. The greatest loss will be to the patients who might have benefited from innovation and development that did not occur.

The need to encourage invention and innovation in this country has been expressed and documented by all segments of the economy, both public and private, and has received Constitutional recognition. Innovation in life-saving or life-enhancing medical devices should not be chilled by permitting copiests to wait for the innovator to spend time and money on developing and patenting medical devices and then to exploit and detract from the patentee's market in the face of a valid and otherwise enforceable patent.

The Federal Circuit's judicial legislation below has deprived the medical device industry of the opportunity to advise Congress of the direct adverse impact on them and the general public of applying Section 271(e)(1) to their products. See generally Pet. App. 11(a). The court below plainly did not appreciate this impact when it stated that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only . . ."

Given the prohibitions in the Constitution's taking clause, it is questionable whether Congress itself could have by law restricted a patent owner's rights as did the Court below. Most certainly, however, the rights possessed by owners of medical device patents cannot be taken away under the guise of statutory interpretation in the face of clear, contrary statutory language and congressional intent.

CONCLUSION

The decision of the Federal Circuit below, in an area where it has no special expertise, is a clear error of law. It will have a direct adverse impact on companies which innovate, develop, and market medical devices, and consequently on those who would benefit from such devices. The impact extends far beyond the parties to this case. Patent owners in this field now hold patents which cannot be enforced against unlicensed use, even though the unlicensed users reap significant benefits, both economically and business-wise.

This disincentive to innovation arises from a plain error in statutory construction. This clear error of law should be corrected by this Court.

Respectfully submitted,

RUDOLF E. HUTZ
Counsel of Record
R. ERIC HUTZ
CONNOLLY, BOVE, LODGE & HUTZ
1220 Market Street
Wilmington, Delaware 19801
(302) 658-9141
Counsel for Amici Curiae
Pfizer Hospital Products
Group, Inc. and Pfizer Inc.

Of Counsel:
PETER C. RICHARDSON
LAWRENCE C. AKERS
MARVIN R. FRANK
PFIZER INC.
235 East 42nd Street
New York, NY 10017